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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,215	08/07/2003	Rebecca Gottlieb	047711-0316	3315

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Foley & Lardner LLP
555 South Flower Street
Suite 3500
Los Angeles, CA 90071-2411

EXAMINER	
GRAY, PHILLIP A	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/638,215	GOTTLIEB ET AL.	
	Examiner	Art Unit	
	Phillip Gray	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 49-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 49-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/7/2010, 1/13/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to applicant's communication of 9/15/2010. Currently amended and newly added claims 1-23 and 49-73 are pending and rejected.

Response to Arguments

Applicant's arguments filed 9/15/2010 have been fully considered but they are not persuasive. Examiner is of the position that Adair does disclose a sensor other then an image recording sensor, since it is simply a "image sensor" (not necessarily recording), and further as stated in the rejection below, Mauze discloses substituting other sensors (electrochemical/biological/oxygen type sensor) in order for effective sampling and analyzing of a physiological fluid for desired characteristics. Further these sensors would comprise a catalyst or enzyme that reacts to a biological or chemical parameter. See rejection below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11,14-23 and 49-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry (U.S. Patent Application Number US2002/0077592 A1) in view of Adair et al. (U.S. Patent 6,211,904) in further view of Mauze et al. (U.S. Patent 6,375,627). Barry discloses a replenishable stent and drug delivery system (see figures 1-16 and paragraphs at [0002]-[0048] generally, specific embodiments at [0067]-[0097]). Barry discloses a method for mitigating restenosis at a trauma site (where a stent is located) within the vasculature comprising: positioning a balloon catheter adjacent, interior to the stent, before or after a stent procedure, at a trauma site; and extending a sensor through a lumen in the catheter and through the stent (see element 255 and figures 11,13-15); and delivering a restenosis mitigating drug through apertures in the balloon catheter, upstream to the trauma site. The Barry sensor (255) sensing element is located on one side of and is spaced from the stent (as in figure 13) and the outlet of the catheter is located on the opposite side of the stent at which the sensing element is located, so that the stent is between the outlet and sensor.

Barry discloses the balloon catheter abuts a wall of the vasculature at the trauma site after the balloon catheter is expanded and also adjusting the flow rate and dispersal pattern of the restenosis mitigating drug. Barry further discloses using a restenosis

mitigating agent or drug, which would include the use of insulin, nitric oxide, antibody, steroid , interleukin, blood thinner, ect. (see paragraph [0075]).

Barry discloses the claimed invention except for the step of extending the sensor "through the stent to a position located outside of the catheter and outside of the stent", and "positioning a sensor movable relative to the catheter and the stent" and through the first and second ends of the stent and through the catheter (and the sensor is movable/spaced apart in the direction in which blood flows out of the stent). Adair et al. teaches that it is known to use the step of extending the sensor through the stent to a position located outside of the catheter and outside of the stent. Further Adair teaches extending the sensor "through the stent to a position located outside of the catheter and outside of the stent", and "positioning a sensor movable relative to the catheter and the stent" and through the first and second ends of the stent and through the catheter (and the sensor is movable/spaced apart in the direction in which blood flows out of the stent). Examiner draws applicant's attention to Adair figures 1b-2a, 8-9, 12-16a, and paragraphs at columns 5-6, and columns 20-22. These passages disclose a movable sensor on the distal end of the device that is movable relative to a balloon and stent of a catheter, to provide the surgeon an observation and measurement of where the stent is located within the vasculature and in reference to the stent on a low profile device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Barry with the step of extending the sensor "through the stent to a position located outside of the catheter and outside of the stent" (and moavable relative to the balloon and stent – spaced apart in a direction in

which blood flows) as taught by Adair, since such a modification would provide the method with the step of extending the sensor "through the stent (both ends) to a position located outside of the catheter and outside of the stent" for providing the surgeon an observation and measurement of where the stent is within the vasculature on a low profile device.

It is examiners position that Adair does disclose using a sensor that is not an image **recording** device. Adair uses the term "image sensor" which doesn't necessarily means the Adair image sensor device records what it is viewing (sensing) and further the image sensor is not disclosed as also "recording" any information. However in the alternative and for newly added claims 70-73. It would be an obvious modification to substitute a biochemical/oxygen type sensor to provide an appropriate means to analyze the operation environment for the necessary levels.

Barry in view of Adair discloses the claimed invention except for the sensor being not an image recording device and an electrochemical/biological/oxygen type sensor (as specificed in claims 70-73). Mauze teaches that it is known to use an electrochemical/biological/oxygen type sensor as set forth in abstract and further in paragraphs at columns 7-8 and 11-12 to provide a means to sample and analyze a physiological area or fluid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Barry in view of Adair with an electrochemical/biological/oxygen type sensor as taught by Mauze, since such a modification would provide the system with an

electrochemical/biological/oxygen type sensor for providing a means to sample and analyze a physiological area or fluid.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view Adair in further view of Silver (U.S. Patent Number 6,442,413). Silver discloses an implantable glucose sensor that can be used for implantation in a blood vessel.

Barry in view Adair discloses the claimed invention of a method for mitigating restenosis at a trauma site at which a stent and catheter and sensor are located except for the sensor sensing analyte or glucose. Silver teaches that it is known to use a method where the delivery of the restenosis mitigating drug is modified in response to the sensing of analyte by a sensor as set forth beginning at paragraphs at column 6 line 65 to provide a means to monitor and control glucose levels in the environment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Barry in view Adair with delivery of the restenosis mitigating drug is modified in response to the sensing of analyte by a sensor as taught by Silver since such a modification would provide the method to treat restenosis with a sensor for sensing analyte for providing a means to monitor and control glucose levels in the environment.

Claims 4, 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view Adair. Barry in view Adair discloses the claimed invention except for the specific mention of using the specific drugs. Examiner believes these drugs to be

implicitly stated in the Barry in view Adair reference and thus an appropriate rejection. However if not directly disclosed in Barry in view Adair, they are obvious. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a restenosis mitigating drug of insulin, nitric oxide, antibody, steroid , interleukin, blood thinner, ect, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).*

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/
Examiner, Art Unit 3767

/Theodore J Stigell/
Primary Examiner, Art Unit 3763